DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Orthofix Srl
% Ms. Cheryl Wagoner
Principal Consultant
Cheryl Wagoner Consulting
Po Box 15729
Wilmington, North Carolina 28408

December 8, 2014

Re: K141760
Trade/Device Name: Orthofix Galaxy Wrist
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: November 3, 2014
Received: November 4, 2014

Dear Ms. Wagoner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141760

Device Name
Orthofix Galaxy Wrist

Indications for Use *(Describe)*
The Orthofix Galaxy Wrist external fixator is an orthopedic device intended to be used for bone stabilization in trauma and orthopedic procedures, both on adults and pediatric patients as required.

The indications for use include:
- intra-articular or extra-articular fractures and dislocations of the wrist with or without soft tissue damage;
- polytrauma;
- carpal dislocations;
- unreduced fractures following conservative treatment;
- bone-loss or other reconstructive procedures;
- infection.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
(as required by 21 CFR 807.92)

Submitter	Orthofix Srl
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Date Prepared	November 25, 2014

Trade Name	Orthofix Galaxy Wrist
Common Name	External Fixation Device and Accessories
Panel Code	Orthopaedics/87
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Class	Class II
Regulation Number	21 CFR 888.3030
Product Code	KTT

Device Name	**510(k) Number**	**Manufacturer**
Synthes Small External Fixation System	K963618	Synthes
Stryker Hoffmann II MRI Compact External Fixation System	K053038	Stryker
Orthofix Penning Dynamic Wrist Fixator	K955848	Orthofix
Orthofix Galaxy Fixation system	K113770	Orthofix

Description	The Orthofix Galaxy Wrist is a complimentary system for the current Galaxy Fixation system, engineered specifically for the wrist. The primary objective of the Galaxy Wrist is to offer the possibility of distraction/compression and the mobilization of the joint. The device includes various frames, bars, clamps, accessories and instruments. The system is designed to be used with commercially available Orthofix pins. The clamps enable the frame to be coupled to bone by securing the pins/wires for the intended use.

	The system allows the surgeon to: - Position screws where the condition of the bone and soft tissues permits - Reduce the fracture in order to restore alignment

Indications and Intended Use	The Orthofix Galaxy Wrist external fixator is an orthopedic device, intended to be used for bone stabilization in trauma and orthopedic procedures, both on adults and pediatric patients as required. The indications for use include: - intra-articular or extra-articular fractures and dislocations of the wrist with or without soft tissue damage; - polytrauma; - carpal dislocations; - unreduced fractures following conservative treatment; - bone-loss or other reconstructive procedures; - infection.

Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Orthofix Galaxy Wrist is substantially equivalent to the legally marketed Predicates. The Galaxy Wrist is substantially equivalent to the predicate devices in intended use, indications for use, technological characteristics, and labeling. The Galaxy Wrist is comparable to its predicate in size, shape and materials.

Performance Data	The potential hazards have been evaluated and controlled through a Risk Management Plan. All testing met or exceeded the requirements as established by the test protocols and applicable standards. A review of the mechanical data indicates that the components of the Subject device are capable of withstanding expected loads without failure. The Subject device was therefore found to be substantially equivalent to the Predicates. Clinical data was not needed to support the safety and effectiveness of the Subject Device. The following mechanical testing was performed: • ASTM F 1541 “Standard Specification and Test Methods for External Skeletal Fixation Devices” MRI compatibility testing was also conducted per: • ASTM F2182 “Standard test method for measurement of radio frequency induced heating near passive implants during magnetic resonance imaging” • ASTM F2213 “Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment” • ASTM F2052 “Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment”

Conclusion	Based on the indications for use, technological characteristics, materials, and comparison to predicate devices, the Subject Orthofix Galaxy Wrist has been shown to be substantially equivalent to legally marketed predicate devices.